

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MICHIGAN  
SOUTHERN DIVISION

PHILLIP SALDEN,

Plaintiff,

v.

MATRIX INITIATIVES, INC.,  
et al.,

Defendants.

CIVIL ACTION NO. 06-10277

DISTRICT JUDGE SEAN F. COX

MAGISTRATE JUDGE DONALD A. SCHEER

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**ORDER GRANTING DEFENDANTS' MOTION TO EXCLUDE THE  
EXPERT REPORT AND TESTIMONY OF ALAN R. HIRSCH, M.D.**

Defendants' Motion to Exclude the Expert Report and Testimony of Plaintiff's Expert Alan R. Hirsch, M.D. was referred to the undersigned magistrate judge for hearing and determination. The parties appeared, for hearing, on February 7, 2007. Having reviewed Defendants' motion, together with Plaintiff's response and Defendants' reply, and having heard the arguments of counsel, I find that the motion should be granted.

Federal Rule of Evidence ("FRE") 702 provides that:

[I]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

The judge presiding over a trial must ensure that any scientific testimony or evidence admitted is not only relevant, but also reliable. Daubert v. Merrill Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). While recognizing that there are no absolute certainties in

science, the Supreme Court in Daubert declared that scientific testimony may be admitted so long as it is supported by appropriate validation, based on what is known. Such validation is essential to meeting the “helpfulness” standard of Rule 702. Important questions to be answered in determining whether a theory or technique is scientific knowledge that will assist the trier of fact, or mere speculation, include whether the theory or technique can be, and has been, tested; whether it has been subjected to peer review and publication; and whether it has achieved general acceptance in the scientific community.

The inquiry envisioned by Rule 702 is . . . a flexible one. Its overarching subject is the scientific validity and thus the evidentiary relevance and reliability - of the principles that underlie a proposed submission. The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate.

Daubert, 509 U.S. at 594-95. In summarizing the court’s decision in Daubert, Justice Blackman, writing for the majority, declared that:

‘General acceptance’ is not a necessary pre-condition to the admissibility of scientific evidence under the Federal Rules of Evidence, but the rules of evidence - especially Rule 702 - do assign to the trial judge the task of ensuring that an expert’s testimony both rests on a reliable foundation and is relevant to the task at hand. Pertinent evidence based on scientifically valued principles will satisfy those demands.

Daubert, 509 U.S. at 597.

Plaintiff in the case at bar proposes to offer the testimony of Alan R. Hirsch, M.D., for the proposition that the Plaintiff’s use of Defendants’ product, Zicam, was the cause of Plaintiff’s anosmia.

Case law in this circuit following Daubert requires a trial court to determine whether a proposed expert witness’ testimony qualifies as “scientific knowledge.” Nelson v.

Tennessee Gas Pipeline Co., 243 F.3d 244, 250-51 (6<sup>th</sup> Cir. 2001). Opinions based upon subjective inquiry are liable to exclusion as unreliable. In re: Meridia Prods. Liab. Litig., 328 F.Supp. 2<sup>nd</sup> 791, 806 (N.D. Ohio 2004), aff'd, 447 F.3d 861 (6<sup>th</sup> Cir. 2006). “‘Scientific’ implies a grounding in the methods and procedures of science” and “‘knowledge’ connotes more than subjective belief or unsupported speculation.” Nelson, 243 F.3d at 250. Daubert instructs that scientific testimony, if it is to be admissible, “must be supported by appropriate validation - i.e., ‘good grounds,’ based on what is known.” 509 U.S. at 590. In addition to the basic questions set out in the majority opinion in Daubert, the Federal Rules Advisory Committee suggests additional forms of inquiry in its commentary to the 2000 amendments to Rule 702. Those additional issues include (1) whether the expert has adequately accounted for obvious alternative explanations, and (2) whether the expert is being as careful as he would be in his regular professional work outside his paid litigation consulting. Advisory Committee notes, Fed.R.Evid. 702.

Although the court’s analysis must be flexible, and no single factor identified in Daubert is necessarily dispositive, it is essential to qualification as “scientific knowledge” that the inference or assertion be derived by the scientific method. Daubert, 509 U.S. at 590. Untested and unproven theories are inadmissible. Id. at 592. The overall inquiry is designed to ensure that the expert has applied the same standards of scientific and intellectual rigor to his testimony in court as experts apply to their work in the relevant field. Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 152 (1999).

Plaintiff proposes to present the testimony of Dr. Hirsch regarding his conclusion that Plaintiff’s anosmia was caused by his use of Defendants’ product, Zicam. Dr. Hirsch is a clinician rather than a research scientist. In 2000, he published his clinical observations

regarding a different patient who had suffered the loss of the sense of smell. That patient had also medicated with Zicam, and Hirsch's one paragraph case report raised the possibility that the product can cause anosmia and suggested that the issue was worthy of study. The case report, however, was merely an anecdotal observation, and Hirsch never undertook confirmatory research. (Hirsch Dep., pages 43-45). An untested hypotheses is merely speculation, and does not rise to the level of scientific knowledge. Nelson v. Tennessee Gas Pipeline Co., 243 F.3d 244, 250 (6<sup>th</sup> Cir. 2001); Pride v. BIC Corp., 218 F.3d 566, 578 (6<sup>th</sup> Cir. 2000).

In his deposition testimony, Dr. Hirsch agreed that the scientific method for assessment of causal relationships consists of the formulation of a hypothesis, the design and implementation of experimental procedures to test its validity, scientific observation of the experiment and the drawing of logical conclusions from those observations. (Hirsch Dep., pages 43-44). Based in great part upon his own testimony, I conclude that Dr. Hirsch's conclusions regarding the causation of Plaintiff's anosmia failed to meet the scientific standard required by FRE 702. Dr. Hirsch admits that he failed to formulate a hypothesis that Zicam can cause smell loss. He performed no testing calculated to prove or disprove that proposition, and he cites no specific test data generated by other scientists which supports his causation conclusion.

It is undisputed that Zicam is a cold remedy. Plaintiff used the product in December 2003 because he had a cold. (Salden Dep., pages 92-94, 96, 99). Dr. Hirsch concedes that colds and upper respiratory infections can cause anosmia and that olfactory impairment most commonly originates with an upper respiratory viral infection. (Hirsch Dep., pages 38-39). Impairment of the senses of smell and taste is not uncommon, in

1992, Dr. Hirsch estimated that 4,000,000 Americans had olfactory abnormalities, and that 200,000 people seek medical care annually because of smell or taste related complaints. The witness estimates that those figures are now higher. (Hirsch Dep., pages 62-63). Over 100 medical conditions and numerous medications have been associated with the loss of the sense of smell. Among those are gastroesophageal reflux disease (GERD), hypertension, and the medications Zithromax and Flagyl. Those conditions and medications appear in Plaintiff's medical records for the period prior to his report of olfactory dysfunction. He has also used Zicam in the past. Other circumstances commonly associated with smell loss are long term smoking and aging itself. (Hirsch Dep., pages 63, 67-68, 131-133). Plaintiff has a long history of smoking. Over 50% of individuals over the age of 65 have a major smell impairment, and 50 to 75% of individuals of Plaintiff's age (74) have smell dysfunction. Twenty-Five percent of such individuals have complete loss of olfactory capacity. (Hirsch Dep., pages 63, 131).

Dr. Hirsch's deposition testimony reflects that he lacks basic information about Zicam. The essence of his opinion is that Defendant's product was the cause of Plaintiff's loss of a sense of smell. Nonetheless, he testified that he does not know the product's ingredients. (Hirsch Dep., pages 41-42). The witness' opinion is based upon the assumption that Plaintiff properly used the medication. While he opines that the proper use causes the gel to reach the olfactory epithelium at the top of the nasal cavity, as it must to produce any toxic effects, Dr. Hirsch has never operated (much less tested) the applicator. (Hirsch Dep., page 42). The olfactory epithelium is a relatively small patch of sensory cells situated high in the rear of the nose and protected by the complex anatomical architecture of three turbinates whose function is to filter out particles in the airway. Dr. Hirsch has

done nothing to investigate whether Zicam actually does reach the olfactory epithelium when the product is used as directed. (Hirsch Dep., pages 42, 48-49, 213, 215, 217). He has not reviewed any of the research on Zicam's distribution pattern within the nose<sup>1</sup> or any animal toxicity research<sup>2</sup> on the product. (Hirsch Dep., pages 40-41, 46, 213, 215, 217). Dr. Hirsch never undertook any follow-up study or research to support his published case report suggesting that Zicam adversely affects the sense of smell. (Hirsch Dep., pages 40-41, 45).

Plaintiff's medical condition at the time of his use of Zicam may have affected the likelihood of distribution of Zicam to the olfactory epithelium. Mr. Salden was apparently congested at the time of his use of the product, suggesting a reduction in the scope of distribution. (Hirsch Dep., pages 48, 92-94, 188-89). Plaintiff also has a history of chronic breathing obstruction due to a deviated septum. (Hirsch Dep., pages 56, 60-64, 235; Girgis Dep., pages 19-20). The impact of those circumstances is not scientifically addressed by the proposed expert witness. They are essentially disregarded.

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<sup>1</sup> Dr. Hirsch has not read the scientific literature indicating that viscous solutions like Zicam do not reach the superior nasal cavity, due to nasal anatomy, mucus flow, and basic principals of fluid dynamics. (R. Dalby Report, page 9). Dr. Hirsch has not read the scientific literature in this area. He has conducted no testing of distribution patterns of Zicam gel, and has not reviewed the data from existing studies which contradict his opinion. (Hirsch Dep., pages 48-49, 213, 215, 217).

<sup>2</sup> Dose-response testing of Zicam has been performed on animals. Results indicate that applying Zicam to the olfactory epithelium in the mouse at several times the equivalent of the dose administered by human use of the produce has no effect on smell tissue or function. (Slotnik Abstract). Dr. Hirsch has not reviewed this data. (Hirsch Dep., pages 40-41). He concedes that he lacks the expertise to evaluate the applicability of animal research to human experience. (Hirsch Dep., pages 71-73).

Dr. Hirsch relies heavily upon the temporal relationship between Plaintiff's use of Zicam and his development of olfactory impairment to support the opinion that Zicam was the cause. (Hirsch Dep., pages 161, 172). As Defendant correctly observes, however, the temporal relationship between Plaintiff's cold and his loss of the sense of smell is indistinguishable from the temporal relationship between his use of Zicam and his impairment. Similarly, Dr. Hirsch elected to rule out upper respiratory infection, age, smoking and other potential causes of Plaintiff's loss of his sense of smell. In each instance, however, the witness offers no authoritative scientific source to support his conclusions. Furthermore, the record relating to the onset and progress of Plaintiff's olfactory loss is far from unequivocal.

In summary, Dr. Hirsch's conclusion that Zicam can cause loss of the sense of smell when used as directed is not supported by any testing, and is contradicted by research performed by others. The witness has not subjected his analysis to any form of objective scientific verification. Plaintiff has failed to establish that the theory that Zicam causes olfactory impairment when used as directed is generally accepted in the scientific community. Most importantly, in my view, Dr. Hirsch has failed to properly account for other reasonable causal explanations for Plaintiff's impairment. I am satisfied that the opinion proffered by Dr. Hirsch is not supported by "scientific knowledge" within the intent and purpose of FRE 702, as applied in Daubert and subsequent cases.

For all of the above reasons, Defendants' Motion to Exclude the Expert Report and Testimony of Plaintiff's Expert Alan R. Hirsch, M.D. is granted.

s/Donald A. Scheer  
DONALD A. SCHEER  
UNITED STATES MAGISTRATE JUDGE

DATED: March 16, 2007

### **CERTIFICATE OF SERVICE**

I hereby certify on March 16, 2007 that I electronically filed the foregoing paper with the Clerk of the Court sending notification of such filing to all counsel registered electronically. I hereby certify that a copy of this paper was mailed to the following non-registered ECF participants on March 16, 2007. **None.**

s/Michael E. Lang  
Deputy Clerk to  
Magistrate Judge Donald A. Scheer  
(313) 234-5217